

REMARKSRegarding the Status of the Claims:

Claims 1 – 226 are pending.

Claims 40 – 111 have been withdrawn from consideration.

Regarding the Claim Amendments presented in this reply:

The amendments to the claims do not add new matter.

- Claim 1 has been amended as suggested on pages 3 and 4 of the Office action. These amendments find support on page 1, line 27, and on page 2, line 13 of the specification.
- Claims 6, 24, 120, 140, 160, 180, 200, and 226 have been amended as suggested on page 4 of the Office action.
- Claims 5, 119, 120, 199, 219, and 225 have been amended as suggested on page 6 of the Office action. Please note that claim 120 rather than 130 has been amended.
- Claims 1, 135, and 195 have been amended to include a step of outputting the estimate to a user. Claims 19, 155, and 215 have been amended to indicate that the processor is programmed to output the estimate. Claim 38 has been amended to indicate that the computer program logic comprises the step of outputting the estimate. Support for these amendments is found on page 22, line 6; page 23, line 8; page 23, line 12; page 24, line 9; page 60, line 24; Table 5C; and page 96, line 12 of the specification.

Regarding the Amendments to the Specification presented in this reply:

The amendments to the specification add no new matter. The amendment repeats (parenthetically) the generic descriptions of the trademarked names already present on page 23, at indicated lines 19 – 27.

Regarding the Objections to the Specification:

The objections to the specification are moot in light of the amendments presented in this reply.

Regarding the Objections to the Claims:

The objections to the claims are moot in light of the amendments presented in this reply, which spell out the acronyms as requested. However for the record it is noted that because claim language is to be interpreted not in a vacuum but in light of the specification, there is nothing objectionable about use in claims of acronyms that are defined in the specification.

Regarding the Claim Rejections:

The Office action rejects:

- I. claims 1 – 39 and 112 – 226 under 35 U.S.C §101;
- II. claims 5, 119, 130, 199, 219, and 225 under 35 U.S.C §112, second paragraph; and
- III. claims 1, 19, 37, 38, 135, 155, 195, and 215 under 35 U.S.C §102(b) over Cox et al., *Journal of Endocrin. and Metab.* (1994) Vol. 79, No. 6, pages 1659 – 1562; PTO 1449 reference (hereinafter, “Cox”); and

- IV. claims 1, 5, 19, 23, 37, 38, 135, 139, 155, 159, 195, 199, 215, and 219 under 35 U.S.C §102(b) over Kovatchev et al., *Journal of Theor. Med.* (2000), pages 1 – 10; PTO 1449 reference, (hereinafter, “Kovatchev”).

Regarding Rejection I:

Applicants respectfully submit that the rejection of claims 1 – 39 and 112 – 226 under 35 U.S.C §101 should be withdrawn. The claims have been amended as suggested, wherein the results are outputted to a user, and thereby provide a practical application that produces a useful result, such as evaluating blood glucose levels of a diabetic patient and enabling the patient to manage their condition.

Regarding Rejection II:

Applicants respectfully submit that the rejection of claims 5, 119, 130, 199, 219, and 225 under 35 U.S.C §112, second paragraph should be withdrawn. This rejection is moot in light of the claim amendments made in light of the comments in the Office action.

Regarding Rejection III:

Applicants respectfully submit that the rejection of claims 1, 19, 37, 38, 135, 155, 195, and 215 under 35 U.S.C §102(b) over Cox et al. should be withdrawn.

The Office action asserts, page 1659, column 2 of Cox teaches a method and system to monitor blood glucose (BG) over periods of time intervals, wherein HbA_{1c} levels are determined. The Office action also asserts that page 1660, column 1 of Cox teaches mathematical formulae were used to determine the data parameters.

The present claims require preparing blood glucose (BG) data for estimating HbA_{1c}, using a predetermined sequence of mathematical formulas defined as: pre-processing of the data; estimating HbA_{1c} using at least one of four predetermined formulas; and validation of the estimate via sample selection criteria. Finally, the present

claims require outputting the estimate of HbA_{1c}. Column 1, page 1660 of Cox does not describe estimating HbA_{1c} based on collected BG data. Instead, the reference explains “Glycosylated Hb was determined at the same laboratory for all readings, using a bornate affinity column chromatography method.” Thus, it is evident that the glycosylated Hb was not estimated based on BG data. The mathematical formulae to which the Office action refers were employed to rescale the BG readings and generate the curve depicting the weighted risk for specific BG values, presented in Fig. 1. Indeed, as stated in the Abstract of Cox, the goal of the study “was to determine whether the frequency of severe hypoglycemia could be predicted by ... predictor variables [including the] level of glycemic control measured by glycosylated hemoglobin-A1 (HbA1).” Thus, Cox does not anticipate the present invention, which relates to estimating HbA_{1c} based on collected BG data.

Regarding Rejection IV:

Applicants respectfully submit that the rejection of claims 1, 5, 19, 23, 37, 38, 135, 139, 155, 159, 195, 199, 215, and 219 under 35 U.S.C §102(b) over Kovatchev et al. should be withdrawn.

The Office action asserts that the abstract and the “procedure” section of Kovatchev teaches a computational system and method of monitoring BG levels and assessing HbA_{1c}. The Office action fails to establish a *prima facie* case of anticipation, because the claims are not directed to “monitoring BG levels and assessing HbA_{1c}.” The claims require estimating HbA_{1c} from collected BG data. The Abstract of Kovatchev states, “[w]e suggest a computational procedure based on a symmetrization of the BG measurement scale and on a superimposed BG risk function, that allows for computation of two glycemic control markers: the Low BG Index (LBGI) and the High BG Index (HBGI).” According to page 3 of the reference, the goal of the research reported “was to study risk factors for [severe hypoglycemia]” The procedure section explains that “[a]t one-month meetings the participants’ ... blood was drawn for HbA_{1c} determination.”

Again, the present claims require preparing BG data for estimating HbA_{1c}, using a

predetermined sequence of mathematical formulas defined as: pre-processing of the data; estimating HbA_{1c} by applying at least one of four predetermined formulas to the BG data; and validation of the estimate via sample selection criteria. Finally, the present claims require outputting the estimate of HbA_{1c} . The Kovatchev reference does not describe estimating HbA_{1c} based on collected BG data. Thus, Kovatchev does not anticipate the present invention.

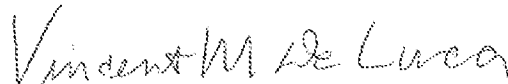
In Conclusion:

In view of the foregoing, claims 1-39 and 112-226 are submitted to be patentable over the prior art of record, and the present application is submitted to be in condition for allowance. The Examiner is authorized to cancel claims 40-111 without prejudice to the filing of one or more divisional applications, in the event that claims 1 – 39 and 112 – 226 are allowed. Applicants request favorable action in this matter. In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner is welcome to contact the undersigned by phone to further the discussion.

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